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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/486,660	10/29/2001	Maria Grazia Sacco	SCBREV-223	8756

2292 7590 12/24/2003

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EXAMINER

PRIEBE, SCOTT DAVID

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 12/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/486,660

Applicant(s)

SACCO ET AL.

Examiner

Scott D. Priebe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-28,33,34 and 36-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-28,33,34 and 36-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 February 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 20000228. 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election of group V in the paper filed 9/5/03 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). All claims directed to non-elected inventions have been cancelled. Claims 23-28, 33, 34, and 36-40 are directed to invention V, and are under examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 23-28, 33, 34, and 36-40 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Sacco et al. (Nature. Biotech. 15 (12): 1392-1397, Dec. 1997).

Sacco discloses a method for in vivo analysis of heat and metal toxicity (Rb, Cr, Cu, Hg, As and Cd) using a transgenic mouse whose genome comprises the promoter of the human *hsp70*

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gene functionally linked to coding sequence for human growth hormone, including kinetic analysis and repeat administration to the same animals. See entire reference.

This reference was authored jointly by the inventors of the instant application and Bagnasco, Chiesa, Parolini, and Cato, and thus constitutes description by others under § 102(a). Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claims 23, 25-28 and 33 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Guven et al. (Aquatic Toxicology 29: 119-137, 1994).

Guven discloses a method of in vivo analysis of heat and metal toxicity (e.g. Hg, Cd) using transgenic *Caenorhabditis elegans* comprising a construct of a heat-shock promoter (of the *Drosophila melanogaster hsp70* gene) functionally linked to a reporter gene sequence encoding β -galactosidase. The *C. elegans* are exposed to the agent and the expression of the reporter gene is determined. Kinetics assays were also performed. See entire reference.

Claims 23, 25-28 and 33 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Candido et al., CA 2,088,379.

Candido discloses a method of in vivo analysis of heat and metal toxicity (e.g. Hg, Cu, As, Cd) using transgenic *Caenorhabditis elegans* comprising a construct of a heat-shock promoter (of the *C. elegans hsp16* gene) functionally linked to a reporter gene sequence

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encoding β -galactosidase. The *C. elegans* are exposed to the agent and the expression of the reporter gene is determined. Kinetics assays were also performed. See entire reference.

Claims 23-25, 33, 34, and 36 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Messing et al. US 6,501,003.

Messing discloses a method for analysis of agents for neurotoxicity using a transgenic mouse whose genome comprises the stress-inducible promoter of the glial fibrillary acidic protein gene operably linked to a sequence encoding green fluorescent protein. The method can be include kinetic analysis and repeat administration to the same animal. See entire reference, e.g. col. 3-4 and claims 2-3.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

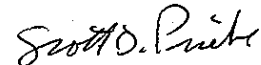
If a certified translation of the priority document is filed and found to support the claimed invention under 35 USC 112, first paragraph, the rejections over Sacco and Messing would be obviated.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (703) 308-7310 (after 1/12/04 – (571) 272-0733). The examiner can normally be reached on M-F, 8:00-4:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Scott D. Priebe
Primary Examiner
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